

Message Text

UNCLASSIFIED

PAGE 01 STATE 145345
ORIGIN HEW-06

INFO OCT-01 EA-09 ISO-00 OES-07 EB-07 COME-00 SNM-02
DEAE-00 TRSE-00 NSC-05 /037 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP:JFRY
DHEW/PHS/OASH/OIH: RBUHRICH, M.D.
EA/IMS:ARDORNHEIM(INFO)

-----050330 230234Z /70

P 222229Z JUN 77
FM SECSTATE WASHDC
TO AMEMBASSY JAKARTA PRIORITY

UNCLAS STATE 145345

E.O. 11652: N/A

TAGS: BGEN, OGEN, ETRD, EIND, TBIO, ID

SUBJECT: FIRM REQUESTS FDA (FOOD AND DRUG ADMIN-
ISTRATION) INSPECTION

REF: JAKARTA 7345

1. FDA ADVISES THAT ITS BUREAU OF DRUGS, WISHES TO HAVE
FACILITIES OF FIRM P. T. KEMIA FARMA INSPECTED BY REPRES-
ENTATIVE OF FDA'S FOREIGN INSPECTION PROGRAM TO ASCERTAIN
ABILITY OF FIRM TO ADHERE TO GMP (GOOD MANUFACTURING PRAC-
TICE) REGULATIONS WITH PARTICULAR REFERENCE TO THE DRUG
QUINIDINE SULFATE.

2. NEXT SCHEDULED INSPECTION TO ASIAN AREA TENTATIVELY
ARRANGED FOR AUGUST 1977. NO CHARGE WOULD BE MADE BY FDA
FOR THIS TYPE OF INSPECTION.

3. FDA DOES NOT MAINTAIN A LIST OF POSSIBLE CONSULTANTS
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IN ASIAN AREA. THE FOLLOWING IS A PARTIAL LIST OF U.S.
BASED CONSULTANTS WHO MIGHT BE ABLE TO PROVIDE FIRM WITH
EVALUATION OF THEIR MANUFACTURING PRACTICES:

(A) CHECCI AND COMPANY
1730 RHODE ISLAND AVENUE, N.W.
WASHINGTON, D.C. 20006

(B) HOWARD B. MELSON
2409 LAKEVALE DRIVE
VIENNA, VIRGINIA
TELEPHONE 703-281-2550

(C) DR. WILLIAM ELIAS
1135 SOUTH CONCORD ROAD
WEST CHESTER, PENNSYLVANIA 19380
TELEPHONE 215-399-0589

(D) DR. JOSEPH DILORENZO
BOX 172
CHINCOTEAGUE, VIRGINIA 23336
TELEPHONE 804-336-5515

(E) DR. ROBERT UMDENSTOCK, PRESIDENT
GRIFFIN-RUTGERS COMPANY
373 MAIN STREET
ISLIP, NEW YORK 11751
TELEPHONE 516-277-1500 CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: FOOD INSPECTION, DRUGS, FOODS
Control Number: n/a
Copy: SINGLE
Sent Date: 22-Jun-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE145345
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770223-0835
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770630/aaaaaztl.tel
Line Count: 83
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 2b7b6078-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 77 JAKARTA 7345
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 27-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2067848
Secure: OPEN
Status: NATIVE
Subject: FIRM REQUESTS FDA (FOOD AND DRUG ADMIN- ISTRATION) INSPECTION
TAGS: BGEN, OGEN, ETRD, EIND, TBIO, ID
To: JAKARTA
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/2b7b6078-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
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